REMARKS

Favorable reconsideration is respectfully requested in view of the foregoing amendments and following remarks.

Claims 3-25 and 27-32 are pending.

Claim 22 was objected to for the reasons set forth on page 2 of the Action.

Claim 22 has been amended as suggested by the Examiner. Accordingly, this ground of objection is deemed to be overcome.

Claim 14 was objected to on the basis that it does not further limit the claims from which it depends.

Claim 14 has been rewritten in independent form, incorporating the limitations of claim 3. Accordingly, this ground of objection is deemed to be overcome.

Claims 4-6, 12-13, 15-21 and 24-25 are objected to on the basis that they read on non-elected species. This objection is respectfully traversed. The Examiner is respectfully requested to reconsider the position that the claims must be limited to the elected species. The instant response will establish the patentability of the claimed invention over the cited prior art. Accordingly, the claims should be allowed in their generic form. Reconsideration is respectfully requested.

Claims 3 to 5, 8 to 11, 12 to 14, 16, 19 to 21 were rejected under 35 U.S.C. 112, on the basis that the specification requires a person skilled in the art to use undue experimentation to make and use the claimed invention regarding *Bifidobacteria*. It is the Examiner's position that the specification discloses enough experimentation with respect to the claimed invention relating to *Bifidobacterium longum*, but not with respect to *Bifidobacteria* other than *Bifidobacterium longum*, such as *Bifidobacterium adolescentis, Bifidobacterium bifidum, Bifidobacteirum pseudilongum, Bifidobacterium thermophirum, Bifidobacterium breve, Bifidobacterium infantis* (pages 3-4 of the Office Action). Such position is respectfully traversed.

Applicants respectfully submit that one skilled in the art would be capable of practicing the claimed invention, using the six specific species belonging to *Bifidobacteria* other than *Bifidobacterium longum* according to claim 3, without undue experimentation, taking into consideration the teachings of the specification and the knowledge in the art. The field of gene

therapy has advanced considerably since the 1998 article by Anderson and the other references cited by the Examiner. One skilled in the art would be capable of practicing the claimed invention using the six other claimed bacteria species using routine experimentation. In fact, there is submitted herewith a publication by Li et al., showing that the disclosure by Applicants is enough to carry out a range of the claimed invention with the use of knowledge shared by people in the art even though it is not disclosed in the Examples.

Based on the inventions essentially disclosed by the inventors (Yazawa et al. Cancer Gene Therapy, 2000;7;269-274), the publication by Li et al. (Cancer Gene Therapy, 2003;10;105-111) shows that the inventions relating to *Bifidobacteria* other than *Bifidobacterium longum* can be used to carry out the claimed invention. Specifically, Li et al. shows that *Bifidobacterium adolescentis* was used to carry out the inventions based on the inventors' disclosures together with the knowledge that people skilled in the art had at the time of the invention. The abstract of Li et al. is cited below for reference.

> "In order to overcome difficulties that hampered widespread application of antiangiogenesis in cancer therapy, a highly specific delivery system may be engaged in vivo to deliver and express antiangiogenic genes. We selected a strain of *Bifidobacterium adolescentis* (*B. adolescentis*) as the delivery system to transport endostatin gene to solid tumors. *B. adolescentis* with endostatin gene were injected into tumor-bearing mice through the tail vein. After the mice were sacrificed, the tumor and some normal tissues of the mice were examined. *B. adolescentis* were only found in the tumors and no bacilli were found in other normal tissues. Also, a strong inhibition of angiogenesis had been shown to inhibit local tumor growth in the administration group. These results suggested that *B. adolescentis* only germiunated and proliferated in solid tumors and might be a highly specific and efficient vector for transporting anticancer genes into target tumor in cancer gene therapy."

Applicants would further note that the inventors' paper (Yazawa et al. 2000) is cited as Reference Number 9. Thus, it is respectfully submitted that the pending claims are enabled within the meaning of 35 USC 112.

Withdrawal of the rejection is also warranted by the case of Atlas Powder Co. v. E.I. du Pont de Nemours & Co. 750F.2d 1569, 224 USPQ 409 (Fed. Cir. 1984), and the following citation taken from Donald S. Chisum "Elements of United States Patent Law, Second Edition, 2000, Japanese Edition published by YUSHODO PRESS CO, LTD., Tokyo, 2000, pages 154-157:

> "a claim is not improper if one of ordinary skill in the art would be able to determine readily which embodiments are operable."

Further, it is also stated in In re Strahilevitz, 668 F.2d 1229, 1982 that the disclosure of concrete examples is desirable and effective to satisfy the enablement requirements of the inventions, but is not a necessary to satisfy the disclosure requirements.

It is the position taken by Examiner that the full range of the claimed inventions in the present application cannot be carried out by the disclosure of the specification. In the Final Office Action, it is supported by the citation of some references.

Citing Anderson, Examiner states that the gene therapy

> "still requires several years before it will make a noticeable impact on the treatment of disease, and that several major deficiencies still exit" (p.5 of the Final Office Action).

However, as mentioned above, it is evident from the existence of Li et al. that the range of the claimed inventions can be carried out by the disclosure of the present inventions together with the knowledge of a person skilled in the art. Therefore, it is submitted that the general statement on gene therapy made by Anderson is not applicable to the case of the present application.

Citing Argnani and Yazawa, Examiner states:

> "The state of the art as taught by Argnai and Yazawa display that studies on *Bifidobacterium* at the molecular level are severely limited in the absence of an efficient transformation. Therefore, the state of the art as considered unpredictable and the as-filed specification does not provide sufficient guidance for one skilled in the art to make and/or use a representative number of bacterium from the genus *Bifidobacterium* as gene delivery vectors." (p. 7 of the Final Office Action)

However, as mentioned above, it is evident from the existence of Li et al. that the range of the claimed inventions can be carried out by the disclosure of the present invention together with the knowledge of a person skilled in the art. Therefore, it is submitted that the conjecture on the state of the art based on Argnani and Yazawa is not appropriate.

As a concrete example, Applicants also respectfully submit a copy of USP 5,601,999, a patent already granted by the USPTO, wherein the claimed invention refers to a genus while the examples disclose a species from the genus.

To summarize, as proven by the existence of Li et al., the disclosure of the present application does not require a person skilled in the art to use undue experimentation to carry out the full range of the claimed inventions with the six claimed species from the genus of *Bifidobacterium* other than *Bifidobacterium longum*. As mentioned above, providing examples in the specification is not a necessary condition. Therefore, the present application satisfies both the enablement requirements and the disclosure requirement, and hence satisfies 35 U.S.C. 112.

Accordingly, favorable reconsideration is respectfully requested.

Claims 12-14, 16, 19-21 and 24 are rejected under 35 USC 112, second paragraph, for the recitation "any one of claims 3 to 11".

This ground of rejection is respectfully traversed, on the basis that the generic claims, and claims directed to non-elected species, are patentable over the prior art.

Claims 3, 8 to 9, 12, 14, 16, 19, 21, 24 and 28-31 are rejected under 35 U.S.C. 102 as anticipated by Yazawa et al. (IDS, Cancer Gene Therapy, Vol.7, pp. 269-274, March 2000) or Babincova et al. (Life and Medical Sciences Online, http://intrust,de/lamso/lpext.dll.Infobase0?title0003.htm?fn=docu 8/7/2000, pp.1-4).

Submitted herewith is the Rule 131 Declaration executed by the inventors. Such declaration establishes a date of invention of the claimed invention prior to the publication date of the two references. Accordingly, these grounds of rejection are deemed to be overcome.

It the Final Office Action, it is also stated:

"In addition, as stated in the traversal, "5 out of 7 researchers listed on the article are inventors for the claimed invention". However, there is no evidence that the other 2 researchers should not be listed as co-inventors." (p.11 of the Final Office Action)

Applicants do not understand this suggestion. The present inventors are establishing a date of invention under 37 CFR 1.131, which is earlier than the publication dates of the cited references. The inventorship of the application is entitled to a presumption of correctness. There is no basis for requiring a statement by unnamed inventors who are listed as co-authors of a publication. Sometimes a Declaration is submitted under the holding *of In re Katz*, but such declaration is intended to overcome a rejection under 35 USC 102(a). Such is not the case here. There are no defects in the inventorship of this application. Accordingly, favorable consideration of the pending claims is respectfully requested.

Claims 3-5, 8 to 9, 12, 14, 16, 19, 21, 24 and 28-31 were rejected under 35 U.S.C. 103(a) as anticipated by Babincova et al. (Life and Medical Sciences Online, http://www.itrust.de/lamso/lpext.dll.Infobase0?title0003.htm?fn=docu8/7/2000, pp.1-4) together with Tagliabue et al.

This ground of rejection is overcome by the enclosed Declaration.

Accordingly, favorable consideration of the pending claims is respectfully requested. Should the resolution of any minor issues place the application in condition for allowance, the

Examiner is kindly invited to call the undersigned at the designated telephone number.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "**Version with markings to show changes made**."

Respectfully submitted,

Minoru FUJIMORI et al.

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

14. (Twice Amended) [A method for expressing a gene coding for a protein having an antitumor activity in tissue tumors specifically, which comprises use of the bacterium as claimed in any one of Claims 3 to 5 or 8 to 11.] A method for expressing a gene coding for a protein having an antitumor activity in tissue tumors specifically, which comprises use of a bacterium selected from the group consisting of *Bifidobacterium adolescentis*, *Bifidobacterium longum*, *Bifidobacterium bifidum*, *Bifidobacterium pseudolongum*, *Bifidobacterium thermophirum*, *Bifidobacterium breve*, *Bifidobacterium infantis*, wherein said bacterium *is* transformed with a recombinant DNA, said DNA is used as a gene delivery vector, and said DNA delivered specifically to tumor tissues under anaerobic conditions is expressed in the tumor tissues.

22. (Twice Amended) A genetically modified bacterium, wherein the bacterium is a *Bifidobacterium longum* 105-A/pBLES100-S-eCD E having the deposit accession number (FERM BP-7274).

32. (Amended) A method of specifically delivering to tumor tissues under anaerobic conditions a genetically modified bacterium, wherein the genetically modified bacterium is a *Bifidobacterium longum*, which the genetically modified bacterium comprises an expression vector comprising a DNA sequence coding for a protein,
the expression vector has a promoter and terminator that specifically function in *Bifidobacterium longum*,
[The method as claimed in Claim 31, wherein] the promoter is a nucleotide sequence consisting of nucleotides 1 to 192[-positions in] of SEQ ID NO: 1, and the terminator is a nucleotide sequence consisting of nucleotides 472 to 600 of SEQ ID NO: 1.

ELEMENTS OF UNITED STATES PATENT LAW

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Toky 2000

英和対訳

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percent of a recognized standard. Prior art methods produced only about 50 percent f the standard. Though the applicant had a patentable invention, a claim to all such hormones with a potency in excess of 100 percent (which would cover hormones with a potency in excess of 230 percent) was rejected because the disclosures did not justify the breadth of the claim given the unpredictability of the particular chemical art.[7]

There is no rigid requirement as to the number of examples that must be provided in order to support a broad claim.[8] An inventor may include "prophetic" examples to illustrate the invention.[9]

In *Regents of the University of California*,[10] which concerned application of the written description requirement to generic claims,[11] the Federal Circuit noted that a genus may be enabled "by showing the enablement of a representative number of species within the genus."[12]

A claim may be too broad if it covers a significant number of inoperative embodiments and one of ordinary skill in the art would have to experiment unreasonably to determine which embodiments are operative. For example, a claim to a broad class of chemical compounds is improper if the applicant demonstrates only that a small number of the compounds within the class are actually operative for a stated utility and fails to provide assurance that substantially all of the compounds are useful.[13] On the other hand, a claim is not improper if one of

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[7] *In re* Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970).

Compare Scripps Clinic & Research Foundation v. Genentech, Inc., 927 F.2d 1565, 18 USPQ2d 1001, 18 USPQ2d 1896 (Fed. Cir. 1991) ("Open-ended claims are not inherently improper; as for all claims their appropriateness depends on the particular facts of the invention, the disclosure, and the prior art."; "They may be supported if there is an inherent, albeit not precisely known, upper limit and the specification enables one of skill in the art to approach that limit.").

[8] *In re* Borkowski, 422 F.2d 904, 164 USPQ 642 (CCPA 1970). See also *In re* Ziegler, 992 F.2d 1197, 26 USPQ2d 1600 (Fed. Cir. 1993) ("Although not explicitly stated in section 112, to be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.' . . . Nothing more than objective enablement is required, and therefore it is irrelevant whether this teaching is provided through broad terminology or illustrative examples.").

[9] Atlas Powder Co. v. E.I. du Pont de Nemours & Co., 750 F.2d 1569, 224 USPQ 409 (Fed. Cir. 1984). The inventor should make clear that the examples are not based on actual research or testing. For example, the examples should be described in the present rather than the past tense— (A sample "may be prepared" rather than "was prepared . . .").

[10] Regents of University of California v. Eli Lilly & Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997).

[11] See § 2321.

[12] The court cited the following authorities.

"*See Angstadt*, 537 F.2d at 502-03, 190 USPQ at 218 (deciding that applicants 'are not required to disclose every species encompassed by their claims even in an unpredictable art' and that the disclosure of forty working examples sufficiently described subject matter of claims directed to a generic process); *In re Robins*, 57 C.C.P.A. 1321, 429 F.2d 452, 456-57, 166 USPQ 552, 555 (CCPA 1970) ('Mention of representative compounds encompassed by generic claim language clearly is not required by § 112 or any other provision of the statute. But, where no explicit description of a generic invention is to be found in the specification . . . mention of representative compounds may provide an implicit description upon which to base generic claim language.'); *Cf. Gostelli*, 872 F.2d at 1012, 10 USPQ2d at 1618 (determining that the disclosure of two chemical compounds within a subgenus did not describe that subgenus); *In re Grimme*, . . . 274 F.2d 949, 952, 124 USPQ 499, 501 (CCPA 1960) ('[I]t has been consistently held that the naming of one member of such a group is not, in itself, a proper basis for a claim to the entire group. H wever, it may not be necessary to enumerate a plurality of species if a genus is sufficiently identified in an application by "other appropriate language." ') (citations omitted)."

[13] *In re* Corkill, 771 F.2d 1496, 226 USPQ 1005 (Fed. Cir. 1985) (claims which include a substantial measure of inoperativeness may be rejected under Section 112 because, during prosecution, the applicant may

製造方法を開示した。一方、先行技術は標準の約50%の効能しか持っていなかった。出願人の発明は特許性を有しているが、100%を超える効能を持つホルモン全てを含むクレーム（これには230%を超える効能を持ったホルモンも含まれてしまう）は、特定の化学分野における予測不可能性という点を考慮して、その開示の範囲がクレームの範囲と適合していないとして拒絶された。[7]

広いクレームを裏付けるために必要な実施例の数について、厳密な要件はない。[8] 発明者は、発明を説明する「予言的な」例を含むことができる。[9]

Regent of the University of California事件で、[10] 属概念に係るクレームに対する記述要件の適用が問題となっているが、[11] 連邦巡回控訴裁判所は、属概念の発明は「ある属に含まれる種を代表できる程度の数の実施可能な開示を行った場合に」実施可能要件を充たしていると判断することができると述べている。[12]

クレームは、意図したように機能しない実施例を相当数含み、どの実施例が実施可能かを判断するために、発明が属する分野の通常の知識を有する者が不合理にたくさんの実験を行う必要がある場合、広すぎると判断される。例えば、ある広いクラスの化合物に係るクレームは、そのクラスに含まれる化合物の少数について、明細書に記載した用途の通り機能することを説明しても、大多数の化合物については用途通り機能することを確信させる開示がなければ、不当に広いクレームであると判断される。[13] 一方、当該分野において通常の知識を有する者が、どの実施例について用途通

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[7] *In re* Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970). Scripps Clinic & Research Foundation v. Genentech, Inc., 927 F.2d 1565, 18 USPQ2d 1001, 18 USPQ2d 1896 (Fed. Cir. 1991)と比較のこと（「限界のないクレームは必ずしも不適当ということはない。全てのクレームについて、適法性は発明、開示の内容、及び先行技術に関する個別の事実に基づいて判断される」。「正確に知られているわけではなくても、上限が内在しており、当業者がその限界を明細書から理解できる場合にはクレームは開示に支持されている」）。

[8] *In re* Borkowski, 422 F.2d 904, 164 USPQ 642 (CCPA 1970). *In re* Ziegler, 992 F.2d 1197, 26 USPQ2d 1600 (Fed. Cir. 1993)も参照（「第112条に明示的に規定されているのではないが、実施可能要件を充足させるためには、特許明細書は、当業者が『不当に多数の実験』を行わなくとも、クレームに含まれる発明の範囲全てを作り理解できるよう記載されていなくてはならない。… 客観的な実施可能性のみが要求されるので、開示の内容が広い概念の用語で説明されていても具体例で説明されていても関係ない」）。

[9] Atlas Powder Co. v. E.I. du Pont de Nemours & Co., 750 F.2d 1569, 224 USPQ 409 (Fed. Cir. 1984). 発明者は具体例が実際の研究や試験に基づくものでないことを明らかにしなくてはならない。例えば、具体例は過去形ではなく現在形で記載すべきである。―― （例を「用意した」ではなく、「用意することができる」）。

[10] Regents of University of California v. Eli Lilly & Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). 96/175

[11] 本書第2321節参照。

[12] 裁判所は、以下の典拠を示した。

「*Angstadt*, 537 F.2d at 502-03, 190 USPQ at 218 参照（出願者は、「予測できない技術においてさえ、クレームによって包含される全ての種類を開示することを要求されない」。そして、40の実施例の開示は、一般的プロセスに向けられたクレームの対象を十分に説明していると判示した）; *In re Robins*, 57 C.C.P.A. 1321, 429 F.2d 452, 456-57, 166 USPQ 552, 555 (CCPA 1970)（「属クレームの用語によって明確に包含された代表例としての化合物への言及は、第112条又はいかなる他の法規の規定によっても要求されない。しかし、属クレームの明確な説明を明細書から見つけることができない場合は、… 代表例としての化合物への言及は、属クレームの用語を基礎づけるものとしての明確な説明となる」）; *Gostelli*, 872 F.2d at 1012, 10 USPQ2d at 1618 と比較せよ（亜属内の二つの化学化合物の開示はその亜属を説明していなかったと判示した）; *In re Grimme*, . . . 274 F.2d 949, 952, 124 USPQ 499, 501 (CCPA 1960)（「このような分類の一つの構成の名称設定は、それだけで、この分類の全てへのクレームの適当な基礎とはならない。しかしながら、一つの属が『他の適切な語句』によって出願に十分に明示されている場合は、種の大多数を列挙することは必要とはならないだろう」）（引用省略）」。

[13] *In re* Corkill, 771 F.2d 1496, 226 USPQ 1005 (Fed. Cir. 1985)（審査経過中に出願人が機能不可能な実施様態を除くクレームの補正を行うことができるので、第112条に基づく機能しない例が含まれているクレームが拒絶さ

rdinary skill in the art would be able to determine readily which embodiments are operable.[14]

A claim that is so broad as to cover products or processes in the prior art is improper because of the novelty and nonobviousness requirements regardless of the adequacy of the disclosure.[15]

Federal Circuit decisions address application of the enablement requirement to patent claims concerning biotechnology. In *Wands*, it held that the PTO erred in rejecting the applicant's claim to immunoassay methods using a specified generic class of antibodies. The applicant made a public deposit of a hybridoma cell line that secreted only one specific monoclonal antibody,[16] but the evidence indicated that those skilled in the monoclonal antibody art could, using the state of the art and applicant's written disclosures, produce and screen other hybridomas secreting other monoclonal antibodies falling within the generic class without undue experimentation.[17] On other hand, in *Wright*, it held that the PTO did not err in rejecting an applicant's broad claims to pathogenic RNA virus vaccines because his specification gave only a single working example, a recombinant vaccine conferring immunity in chickens against a certain RNA tumor virus. The single example and general description "did nothing more than invite experimentation to determine whether other vaccines having in vivo immunoprotective activity could be constructed for other RNA viruses."[18]

In *Amgen*, the court, after upholding a patentee's specific claim to isolated DNA sequences that encode for human erythropoietin (EPO), a protein that increases red blood cell production, found no enablement of the patentee's generic claims to all possible genetic sequences that encode proteins with activity resembling EPO (EPO analogs).[19] It noted that "the number of claimed DNA encoding sequences that can produce an EPO-like product is potentially enormous." "[O]ver 3,600 different EPO analogs can be made by substituting at only a single amino acid position, and over a million different analogs can be made by substituting three amino acids." The specification stated that all EPO analogs can be made but gave details on only a few EPO analogs. A claim to these and similar analogs might be justified but not a claim to all analogs. "Considering the structural complexity of the EPO gene, the manifold possibilities for change in its structure, with attendant uncertainty as to what utility will be possessed by these analogs, . . . more is needed concerning identifying the

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amend the claims to exclude inoperative subject matter); *In re* Cavalitto, 282 F.2d 357, 127 USPQ 202 (CCPA 1960).

[14] Atlas Powder Co. v. E.I. du Pont de Nemours & Co., 750 F.2d 1569, 224 USPQ 409 (Fed. Cir. 1984). In *Atlas Powder*, the court held that a claim to a composition consisting of a combination of three elements was sufficiently supported even though the specification did not give specific amounts as to each element. A person of ordinary skill in the art would be able to select appropriate amounts to suit a particular situation.

[15] See §§ 1300, 1400.

[16] Monoclonal antibodies are discussed at § 1121.3.

[17] *In re* Wands, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). See also Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 231 USPQ 81 (Fed. Cir. 1986).

[18] *In re* Wright, 999 F.2d 1557, 27 USPQ2d 1510 (Fed. Cir. 1993). See also *In re* Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993) (applicant's broad claims to a method for producing *any* mammalian peptide in *any* plant cell were not enabled by a specification giving only a single working example, which involved the dicotyledonous species, tobacco, and a gene coding for gamma-interferon); *In re* Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991) ("Where . . . a claimed genus represents a diverse and relatively poorly understood group of microorganisms, the required level of disclosure will be greater than, for example, the disclosure of an invention involving a 'predictable' factor such as a mechanical or electrical element.").

[19] Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd., 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991). DNA and proteins are discussed at § 1121.2.

り機能するか容易に判断できるときは、クレームが不当に広いとは判断されない。[14]

先行技術である製品又は方法を含むように記載された広いクレームは、開示が適切であっても、新規性と非自明性の要件を充たさないことになる。[15]

連邦巡回控訴裁判所は、バイオテクノロジーに関する特許クレームに対する実施可能要件の適用について、幾つかの判決で判断を行っている。Wands 事件では、特許商標局（PTO）は、特定の属クラスの抗体を使う免疫分析法に係るクレームを拒絶した PTO の判断は誤っていたと判示した。特許出願人はある一つの単クローン抗体のみを分泌するハイブリドーマ細胞ラインを公開寄託したが、[16] この単クローン抗体の分野の通常の知識を有する者は、技術の一般知識及び出願人の明細書の開示に基づいて、クレームで記載する属クラスに属する他の単クローン抗体を分泌する寄託したもの以外のハイブリドーマを過度な実験を行うことなく生産し、スクリーンすることができることを示す証拠が提出された。[17] 他方 Wright 事件では、発病 RNA ウィルスワクチンに係る出願人の広いクレームを、出願人の明細書には、ある種の RNA 腫瘍ウィルスに対し鶏に免疫を作る組み換えワクチンのみが、唯一の実施例として開示されていたことを理由に拒絶した PTO の判断は、誤っていなかったとされた。唯一の実施例と一般的な開示は、「免疫防止活動を持つ他のワクチンが、他の RNA ウィルスに対し作ることができるかを確認する実験を奨励するものでしかない」。[18]

Amgen 事件では、赤血球細胞の生成を増加させる蛋白質である人間のエリスロポエチン（EPO）をコードする分離された DNA 配列に係る特許権者のクレームについては有効性を認めた後で、裁判所は、EPO と同様に活動する蛋白質（EPO アナログ）をコードするゲノム配列を全て含むように記載した特許権者の広い概念に係るクレームについて、実施可能要件を充たしていないとして無効の判断を行った。[19] 裁判所は、「EPO と同様の結果を生じることのできるクレームに含まれる DNA コード配列の数は、無数である可能性がある」と述べた。「3600 以上の EPO アナログを、たった一つのアミノ酸を交換することで作り出すことができる。そして、何百万という EPO アナログを三つのアミノ酸を交換することで作り出すことができる」。明細書には、全ての EPO アナログが生成できると記載されていたが、幾つかの EPO アナログしか詳細が説明されていなかった。開示されたアナログ及びこれに類似するものについてはクレームすることが許されるが、全てのアナログに対しクレームすることは許されない。「EPO ゲノムの複雑性、その構成における無数の変化の可能性とこれらのアナログが持つ用途の予測不可能性に鑑みると、…クレームの範囲に含まれる種々のアナ

れた）； *In re* Cavalitto, 282 F.2d 357, 127 USPQ 202 (CCPA 1960).

[14] Atlas Powder Co. v. E.I. du Pont de Nemours & Co., 750 F.2d 1569, 224 USPQ 409 (Fed. Cir. 1984). Atlas Powder 事件で裁判所は、3 要素の組合せから成る合成物のクレームについて、その明細書において各要素に関し個々の量について記載がなかったにも拘わらず、そのクレームは十分な裏付けとなる開示がなされていると判断した。当該分野において通常の知識を有する者なら、特定の状況にあった適切な量を選択できると判断したためである。

[15] 本書第 1300、1400 節参照。

[16] 単クローン抗体については、本書第 1121.3 節で論ずる。

[17] *In re* Wands, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 231 USPQ 81 (Fed. Cir. 1986) も参照。

[18] *In re* Wright, 999 F.2d 1557, 27 USPQ2d 1510 (Fed. Cir. 1993). *In re* Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993) も参照（あらゆる植物細胞の哺乳ペプチドを生成する方法に係る特許出願人の広いクレームは、双子葉植物類、タバコ、ガンマインターフェロンを符号化する染色体を含む、たった一つの実施例を開示する明細書によって実施可能に支持されていない）； *In re* Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)（「クレームに係る属概念があまり良く理解されていない種類の微生物に関する場合、機械や電気の構成要素のような『予測可能な』要素を含む発明の開示より高いレベルの開示が必要とされる」）。

[19] Amgen, Inc. v. Chugai Pharmaceutical C ., Ltd., 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991). DNA と蛋白質については本書第 1121.2 節で検討する。